

CLAIMS

What is claimed is:

- 5 1. A method for delivering a pharmaceutical via an ocular surface of a mammal, the method comprising contacting the ocular surface of the mammal with a mucoadhesive film that comprises:
- 10 a water-soluble bioadhesive layer to be placed in contact with an ocular surface, the bioadhesive layer including one or more bioadhesive polymers and/or one or more film-forming, water-soluble polymers;
- 15 a water-soluble non-adhesive backing layer that comprises one or more water-soluble, film-forming, pharmaceutically acceptable polymers; and
- one or more pharmaceuticals associated with the bioadhesive layer, associated with the non-adhesive layer, or associated with both the bioadhesive and non-adhesive layers;
- 20 wherein the mucoadhesive film is compatible with ocular surfaces; the mucoadhesive film adheres to ocular surfaces; the mucoadhesive film is flexible; and the mucoadhesive film is water-soluble, biodegradable, and bioerodible in tear fluids.
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2. The method of claim 1 wherein the one or more film-forming water-soluble polymers comprises an alkyl cellulose or a hydroxyalkyl cellulose.

3. The method of claim 1 wherein the one or more film-forming water-soluble polymers comprises hydroxyethyl cellulose (HEC), hydroxypropyl cellulose (HPC), hydroxypropylmethyl cellulose (HPMC), hydroxyethylmethyl
5 cellulose (HEMC), or a combination thereof.

4. The method of claim 1 wherein the one or more film-forming, water-soluble polymers comprises hydroxypropylmethyl cellulose (HPMC).

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5. The method of claim 1 wherein the one or more bioadhesive polymers comprise polyacrylic acid (PAA), sodium carboxymethyl cellulose (NaCMC), polyvinyl pyrrolidone (PVP), or a combination thereof.

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6. The method of claim 1 wherein the one or more water-soluble, film-forming, pharmaceutically acceptable polymers comprise an alkyl cellulose or a hydroxyalkyl cellulose.

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7. The method of claim 1 wherein the one or more water-soluble, film-forming, pharmaceutically acceptable polymers comprise hydroxyethyl cellulose (HEC), hydroxypropyl cellulose (HPC), hydroxypropylmethyl
25 cellulose (HPMC), hydroxyethylmethyl cellulose (HEMC), polyvinylalcohol (PVA), polyethylene glycol (PEG), polyethylene oxide (PEO), ethylene oxide-propylene oxide co-polymers, or a combination thereof.

8. The method of claim 1 wherein the one or more water-soluble, film-forming, pharmaceutically acceptable polymers comprise hydroxyethyl cellulose (HEC), hydroxypropyl cellulose (HPC), or a combination thereof.
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9. The method of claim 1 wherein the one or more water-soluble, film-forming, pharmaceutically acceptable polymers comprise hydroxyethyl cellulose (HEC).
- 10 10. The method of claim 1 wherein the water-soluble non-adhesive backing layer further comprises a non-water soluble lubrication layer.
11. The method of claim 1 wherein the one or more
- 15 pharmaceuticals are independently selected from the group of adrenergic agent; adrenocortical steroid; adrenocortical suppressant; alcohol deterrent; aldosterone antagonist; amino acid; ammonia detoxicant; anabolic; analeptic; analgesic; androgen; anesthesia,
- 20 adjunct to; anesthetic; anorectic; antagonist; anterior pituitary suppressant; anthelmintic; antiacne agent; anti-adrenergic; anti-allergic; anti-amebic; anti-androgen; anti-anemic antianginal; anti-anxiety; anti-arthritic; anti-asthmatic; anti-atherosclerotic;
- 25 antibacterial; anticholelithic; anticholelithogenic; anticholinergic; anticoagulant; anticoccidal; anticonvulsant; antidepressant; antidiabetic; antidiarrheal; antidiuretic; antidote; anti-emetic; anti-epileptic; anti-estrogen; antifibronolytic;
- 30 antifungal; antiglaucoma agent; antihemophilic;

antihermorrhagic; antihistamine; antihyperlipidemia;
 antihyperlipoproteinemic; antihypertensive;
 antihypotensive; anti-infective; anti-infective, topical;
 anti-inflammatory; antikeratinizing agent; antimalarial;
 5 antimicrobial; antimigraine; antimycotic, antinausant,
 antineoplastic, antineutropenic, antiobessional agent;
 antiparasitic; antiparkinsonian; antiperistaltic,
 antipneumocystic; antiproliferative; antiprostatic
 hypertrophy; antiprotozoal; antipruritic; antipsychotic;
 10 antirheumatic; antischistosomal; antiseborrheic;
 antisecretory; antispasmodic; antithrombotic;
 antitussive; anti-ulcerative; anti-urolithic; antiviral;
 appetite suppressant; benign prostatic hyperplasia
 therapy agent; blood glucose regulator; bone resorption
 15 inhibitor; bronchodilator; carbonic anhydrase inhibitor;
 cardiac depressant; cardioprotectant; cardiotonic;
 cardiovascular agent; choleretic; cholinergic;
 cholinergie diagnostic aid; diuretic; dopaminergic
 agent; ectoparasiticide; emetic; enzyme inhibitor;
 20 estrogen; fibrinolytic; fluorescent agent; free oxygen
 radical scavenger; gastrointestinal motility effector;
 glucocorticoid; gonad-stimulating principle; hair growth
 stimulant; hemostatic; histamine H2 receptor antagonist;
 hormone; hypocholesterolemic; hypoglycemic;
 25 hypolipidemic; hypotensive; imaging agent; immunizing
 agent; immunomodulator; immunoregulator;
 immunostimulant; immunosuppressant; impotence therapy;
 inhibitor; keratolytic; LNRN agonist; liver disorder
 treatment; luteolysin; memory adjuvant; mental
 30 performance enhancer; mood regulator; mucolytic; mucosal

protective agent; mydriatic; nasal decongestant;
 neuromuscular blocking agent; neuroprotective; NMDA
 antagonist; non-hormonal sterol derivative; oxytocic;
 plasminogen activator; platelet activating factor
 5 antagonist; platelet aggregation inhibitor; post-stroke
 and post-head trauma treatment; potentiator; progestin;
 prostaglandin; prostate growth inhibitor;
 prothyrotropin; psychotropic; radioactive agent;
 regulator; relaxant; repartitioning agent; scabicide;
 10 sclerosing agent; sedative; sedative-hypnotic; selective
 adenosine A1 antagonist; serotonin antagonist; serotonin
 inhibitor; serotonin receptor antagonist; steroid;
 stimulant; suppressant; symptomatic multiple sclerosis;
 synergist; thyroid hormone; thyroid inhibitor;
 15 thyromimetic; tranquilizer; treatment of amyotrophic
 lateral sclerosis; treatment of cerebral ischemia;
 treatment of Paget's disease; treatment of unstable
 angina; uricosuric; vasoconstrictor; vasodilator;
 vulnerary; wound healing agent; xanthine oxidase
 20 inhibitor; and combinations thereof.

12. The method of claim 1 wherein the one or more
 pharmaceuticals are selected from the group of
 Acebutolol; Acebutolol; Acyclovir; Albuterol;
 25 Alfentanil; Almotriptan; Alprazolam; Amiodarone;
 Amlexanox; Amphotericin B; Atorvastatin; Atropine;
 Auranofin; Aurothioglucose; Benazepril; Bicalutamide;
 Bretylium; Brifentanil; Bromocriptine; Buprenorphine;
 Butorphanol; Buspirone; Calcitonin; Candesartan;
 30 Carfentanil; Carvedilol; Chlorpheniramine;

Chlorothiazide; Chlorphentermine; Chlorpromazine;
 Clindamycin; Clonidine; Codeine; Cyclosporine;
 Desipramine; Desmopressin; Dexamethasone; Diazepam;
 Diclofenac; Digoxin; Digydrocodeine; Dolasetron;
 5 Dopamine; Doxepin; Doxycycline; Dronabinol; Droperidol;
 Dyclonine; Eletriptan; Enalapril; Enoxaparin; Ephedrine;
 Epinephrine; Ergotamine; Etomidate; Famotidine;
 Felodipine; Fentanyl; Fexofenadine; Fluconazole;
 Fluoxetine; Fluphenazine; Flurbiprofen; Fluvastatin;
 10 Fluvoxamine; Frovatriptan; Furosemide; Ganciclovir; Gold
 sodium thiomalate; Granisetron; Griseofulvin;
 Haloperidol; Hepatitis B Virus Vaccine; Hydralazine;
 Hydromorphone; Insulin; Ipratropium; Isradipine;
 Isosorbide Dinitrate; Ketamine; Ketorolac; Labetalol;
 15 Levorphanol; Lisinopril; Loratadine; Lorazepam;
 Losartan; Lovastatin; Melatonin; Methyldopa;
 Methylphenidate; Metoprolol; Midazolam; Mirtazapine;
 Morhpine; Nadolol; Nalbuphine; Naloxone; Naltrexone;
 Naratriptan; Neostgmine; Nicardipine; Nifedipine;
 20 Norepinephrine; Nortriptyline; Octreotide; Olanzapine;
 Omeprazole; Ondansetron; Oxybutynin; Oxycodone;
 Oxymorphone; Oxytocin; Phenylephrine;
 Phenylpropanolamine; Phenytoin; Pimozide; Pioglitazone;
 Piroxicam; Pravastatin; Prazosin; Prochlorperazine;
 25 Propafenone; Prochlorperazine; Propiomazine; Propofol;
 Propranolol; Pseudoephedrine; Pyridostigmine;
 Quetiapine; Raloxifene; Remifentanyl; Rofecoxib;
 repaglinide; Risperidone; Rizatriptan; Ropinirole;
 Scopolamine; Selegiline; Sertraline; Sildenafil;
 30 Simvastatin; Sirolimus; Spironolactone; Sufentanyl;

Sumatriptan; Tacrolimus; Tamoxifen; Terbinafine;
Terbutaline; Testosterone; Tetanus toxoid; THC
Tolterodine; Triamterene; Triazolam; Tricetamide;
Valsartan; Venlafaxine; Verapamil; Zaleplon; Zanamivir;
5 Zafirlukast; Zolmitriptan; Zolpidem; and combinations
thereof.

13. The method of claim 1 wherein the one or more
pharmaceuticals are present in a combined amount of up
10 between about 0.005 wt.% and about 20 wt.% of the
mucoadhesive film.

14. The method of claim 1 wherein the mucoadhesive film
has a thickness of between about 0.1 mm to about 0.5 mm.

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15. The method of claim 1 wherein the mucoadhesive film
further includes a pharmaceutically acceptable
dissolution-rate-modifying agent, a pharmaceutically
acceptable disintegration aid, a pharmaceutically
20 acceptable plasticizer, a pharmaceutically acceptable
coloring agent, a pharmaceutically acceptable
opaquifier, a pharmaceutically acceptable anti-oxidant,
a pharmaceutically acceptable film forming enhancer, a
pharmaceutically acceptable preservative, a component
25 that acts to adjust the kinetics of the erodability of
the mucoadhesive film, or a combination thereof.

16. The method of claim 1 wherein the mucoadhesive film
further includes a third layer located between the
30 water-soluble bioadhesive layer and the water-soluble

non-adhesive backing layer; wherein the third layer is flexible, biodegradable, bioerodible in tear fluids, and water-soluble.

5 17. The method of claim 1 wherein the pharmaceutical is locally delivered.

18. The method of claim 1 wherein the pharmaceutical is systemically delivered.

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19. A method for locally delivering a pharmaceutical via an ocular surface of a mammal, the method comprising contacting the ocular surface of the mammal with a mucoadhesive film that comprises:

15 a water-soluble bioadhesive layer to be placed in contact with an ocular surface, the bioadhesive layer including one or more bioadhesive polymers and/or one or more film-forming, water-soluble polymers;

a water-soluble non-adhesive backing layer that
20 comprises one or more water-soluble, film-forming, pharmaceutically acceptable polymers; and

one or more pharmaceuticals associated with the bioadhesive layer, associated with the non-adhesive layer, or associated with both the bioadhesive and non-
25 adhesive layers;

wherein the mucoadhesive film is compatible with ocular surfaces; the mucoadhesive film adheres to ocular surfaces; the mucoadhesive film is flexible; and the mucoadhesive film is water-soluble, biodegradable, and
30 bioerodible in tear fluids.

20. A method for systemically delivering a pharmaceutical via an ocular surface of a mammal, the method comprising contacting the ocular surface of the
- 5 mammal with a mucoadhesive film that comprises:
- a water-soluble bioadhesive layer to be placed in contact with an ocular surface, the bioadhesive layer including one or more bioadhesive polymers and/or one or more film-forming, water-soluble polymers;
 - 10 a water-soluble non-adhesive backing layer that comprises one or more water-soluble, film-forming, pharmaceutically acceptable polymers; and
 - one or more pharmaceuticals associated with the bioadhesive layer, associated with the non-adhesive
 - 15 layer, or associated with both the bioadhesive and non-adhesive layers;
- wherein the mucoadhesive film is compatible with ocular surfaces; the mucoadhesive film adheres to ocular surfaces; the mucoadhesive film is flexible; and the
- 20 mucoadhesive film is water-soluble, biodegradable, and bioerodible in tear fluids.